



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0158; FRL-9341-5]

***Aspergillus flavus* AF36; Amendment to an Exemption from the Requirement of a Tolerance**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing temporary tolerance exemption for *Aspergillus flavus* AF36 by establishing a permanent exemption from the requirement of a tolerance for residues of the microbial pesticide, *Aspergillus flavus* AF36, in or on pistachio when applied as an antifungal agent and used in accordance with good agricultural practices. On behalf of the Arizona Cotton Research and Protection Council, Interregional Research Project Number 4 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting that EPA amend an existing temporary tolerance exemption for *Aspergillus flavus* AF36. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36 under the FFDCA.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0158. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Jeannine Kausch, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8920; email address: kausch.jeannine@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in

accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0158 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the Federal Register*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2007-0158, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 20, 2011 (76 FR 22067) (FRL-8869-7), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1E7830) by Interregional Research Project Number 4 (IR-4), Rutgers University, 500 College Rd. East, Suite 201W, Princeton, NJ 08540 (on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Ave., Phoenix, AZ 85040-2933). The petition requested that 40 CFR 180.1206 be amended by establishing a permanent exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on pistachio. This notice referenced a summary of the petition prepared by the petitioner, IR-4 (on behalf of the Arizona Cotton Research and Protection Council), which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption and to “ensure that there is a reasonable

certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The nature and toxicological profile of *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, was described extensively in the **Federal Register** of July 14, 2003 (68 FR 41535) (FRL-7311-6). “Those health effects data were the basis for establishing the tolerance exemption for *Aspergillus flavus* AF36 in or on cotton (see the **Federal Register** of July 14, 2003) and corn (see the **Federal Register** of March 23, 2011 (76 FR 16297) (FRL-8868-7)) and their food/feed commodities and also for temporary tolerance exemptions for experimental use of *Aspergillus flavus* AF36 on

pistachio (see the **Federal Register** of May 23, 2007 (72 FR 28868) (FRL-8129-4)) and on corn (see the **Federal Register** of December 26, 2007 (72 FR 72693) (FRL-8342-1)).”

The petitioner has now requested that EPA establish a permanent exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on pistachio by amending 40 CFR 180.1206. EPA reviewed the available data and information in support of this particular action.

Aspergillus flavus AF36 is neither toxic nor infective via the oral and pulmonary routes. EPA has determined that AF36 is practically nontoxic for acute oral effects and slightly toxic for acute inhalation effects. This microbial pesticide has been used for more than a decade in experimental laboratory and field trials and in agricultural practice on cotton in Arizona, California, and Texas without any reports of adverse dermal irritation or hypersensitivity effects. Based on the comprehensive toxicological evaluations set forth in earlier actions establishing tolerance exemptions for *Aspergillus flavus* AF36 in or on cotton (see the **Federal Register** of July 14, 2003) and corn (see the **Federal Register** of March 23, 2011) (also, see Ref. 1), EPA concludes that there are no toxicological endpoints of concern for *Aspergillus flavus* AF36.

IV. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food exposure.* Current uses of *Aspergillus flavus* AF36 include use in or on cotton and corn. Use on pistachios was also permitted under Experimental Use Permit No. 71693-EUP-1, which expired on December 31, 2011. EPA previously evaluated exposure to residues of *Aspergillus flavus* AF36 through food, resulting from this microbial pesticide's use as an antifungal agent in or on cotton and corn, in the **Federal Register** of July 14, 2003 and March 23, 2011. Overall, EPA concluded that human food exposure was not expected with *Aspergillus flavus* AF36's cotton use and was expected (although likely not above *Aspergillus flavus* background levels) with *Aspergillus flavus* AF36's corn use.

As a microbial pesticide for use on pistachio, *Aspergillus flavus* AF36 is intended for a single broadcast soil application from late May to early July. Once applied to pistachio and after exposure to moisture, *Aspergillus flavus* AF36 germinates, using the carrier upon which it is placed as a nutrient source, and displaces aflatoxin-producing strains of *Aspergillus flavus* (Ref. 2). Further, multiple-year studies, which monitored air and soil populations of *Aspergillus flavus*, including strain AF36, in untreated and treated cotton fields, demonstrated replacement of the naturally occurring aflatoxin-producing *Aspergillus flavus* with *Aspergillus flavus* AF36 without an increase in the total population of *Aspergillus flavus* beyond normal background levels (Refs. 3 and 4). Although residues from the use of pesticides containing *Aspergillus flavus* AF36 may be present on pistachios at the time of harvest, commodity processing procedures (e.g., roasting and shelling) may further reduce residues of *Aspergillus flavus* AF36 (Ref. 5).

Should this microbial pesticide be present on food as a result of the cotton, corn, and/or pistachio uses, the results of an acute oral toxicity and pathogenicity study (see

Unit III. of the **Federal Register** of July 14, 2003, as well as Ref. 1) demonstrated that no toxicity, pathogenicity, and/or infectivity is likely to occur with any exposure level of *Aspergillus flavus* AF36 resulting from application as an antifungal agent in accordance with good agricultural practices.

2. *Drinking water exposure.* Similar to the drinking water exposure scenarios described for *Aspergillus flavus* AF36's cotton and corn uses (see the **Federal Register** of July 14, 2003 and March 23, 2011) exposure to residues of this microbial pesticide in consumed drinking water, resulting from pesticidal use in or on pistachio, is possible but not likely to be greater than current/existing exposures to *Aspergillus flavus* strains, which are already present in the environment. Pistachio is grown in an arid environment, which minimizes the potential for transfer of *Aspergillus flavus* AF36 to surface or ground waters that may be used as sources of drinking water. Moreover, the pesticide is applied only once per growing season at a low rate to non-aquatic sites, and offsite movement is not anticipated since the pesticide is in a granular form. If *Aspergillus flavus* AF36 were to be transferred to surface or ground waters (e.g., through runoff) that are intended for eventual human consumption and directed to wastewater treatment systems or drinking water facilities, this soilborne fungus may not survive some of the conditions water is subjected to in such systems or facilities, including chlorination, pH adjustments, and filtration (Refs. 6 and 7).

Should this microbial pesticide be present in drinking water (e.g., water not subject to treatment systems or facilities) as a result of the cotton, corn, and/or pistachio uses, the results of an acute oral toxicity and pathogenicity study (see Unit III. of the **Federal Register** of July 14, 2003, as well as Ref. 1) demonstrated that no toxicity,

pathogenicity, and/or infectivity is likely to occur with any exposure level of *Aspergillus flavus* AF36 resulting from application as an antifungal agent in accordance with good agricultural practices.

B. Other Non-Occupational Exposure

Non-occupational dermal and inhalation exposure is expected to be minimal to non-existent for the uses of *Aspergillus flavus* AF36 in or on cotton, corn, and pistachio. As described previously in the **Federal Register** of July 14, 2003 and March 23, 2011 for *Aspergillus flavus* AF36's cotton and corn uses, this antifungal agent is to be applied to agricultural sites and not in the proximity of residential areas, schools, nursing homes, or day care facilities. Additionally, the *Aspergillus flavus* AF36 product to be applied to cotton, corn, and pistachio is in a granular form, thereby minimizing drift even for application methods (e.g., aerial) that may be more likely to result in offsite pesticide movement and exposure.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA has not found *Aspergillus flavus* AF36 to share a common mechanism of toxicity with any other substances, and *Aspergillus flavus* AF36 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Aspergillus flavus* AF36 does not have

a common mechanism of toxicity with other substances. Therefore, section 408(b)(2)(D)(v) of FFDCA does not apply. For information regarding EPA's efforts to identify chemicals that may have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. This additional margin of exposure (safety) is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

In this instance, based on all the available information, EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Aspergillus flavus* AF36 is used as labeled in accordance with good agricultural practices. As a result, EPA

concludes that no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Moreover, based on the same data and EPA analysis as presented in this unit, the Agency is able to conclude that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *Aspergillus flavus* AF36 when it is used as labeled and in accordance with good agricultural practices as an antifungal agent. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm from this fungus in its use as an antifungal agent via dietary exposure since the microorganism is non-toxic and non-pathogenic to animals and humans. EPA arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit III. of this document).

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated in this document and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue

limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Aspergillus flavus* AF36.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Aspergillus flavus* AF36. Therefore, the existing temporary tolerance exemption for *Aspergillus flavus* AF36 is amended by establishing a permanent exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on pistachio when applied as an antifungal agent and used in accordance with good agricultural practices.

IX. References

1. U.S. EPA. 2003a. *Aspergillus flavus* AF36 Biopesticides Registration Action Document (Dated July 3, 2003). Available from http://www.epa.gov/oppbppd1/biopesticides/ingredients/tech_docs/brad_006456.pdf.
2. U.S. EPA. 2011. *Aspergillus flavus* AF36 use on pistachio. Memorandum from J.V. Gagliardi, Ph.D. and J.L. Kough, Ph.D. to S. Bacchus dated September 29, 2011.

3. U.S. EPA. 2003b. Environmental Hazard Assessment for the Microbial Pesticide, *Aspergillus flavus* AF36 for Conditional Registration in Arizona and EUP Extension in Texas. Memorandum from G.S. Tomimatsu, Ph.D. and Z. Vaituzis, Ph.D. to S. Bacchus dated May 16, 2003. Available from <http://www.epa.gov/pesticides/chemical/foia/cleared-reviews/reviews/006456/006456-2003-05-16a.pdf>.

4. U.S. EPA. 2003c. BPPD Review of Soil and Air Monitoring Studies and Product Performance Testing (Efficacy) Submitted by USDA Southern Regional Research Center/IR-4 as a Condition of Registration and EUP Extension (Texas) for *Aspergillus flavus* AF36. Memorandum from G.S. Tomimatsu, Ph.D. and J. Kough, Ph.D. to S. Bacchus dated May 15, 2003. Available from <http://www.epa.gov/pesticides/chemical/foia/cleared-reviews/reviews/006456/006456-2003-05-15a.pdf>.

5. U.S. EPA. 1996. Microbial Pesticide Test Guidelines – Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm.

6. Centers for Disease Control and Prevention. 2009. Drinking Water - Water Treatment. Available from http://www.cdc.gov/healthywater/drinking/public/water_treatment.html.

7. U.S. EPA. 2004. Primer for Municipal Wastewater Treatment Systems. EPA 832-R-04-001. Available from <http://www.epa.gov/npdes/pubs/primer.pdf>.

X. Statutory and Executive Order Reviews

This final rule amends a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are amended on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 29, 2012.

Keith A. Matthews,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1206 is amended by revising paragraph (b) to read as follows:

§180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

* * * * *

(b) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* AF36 in or on pistachio when applied as an antifungal agent and used in accordance with good agricultural practices.

* * * * *